REMARKS

The specification and abstract have been amended to correct minor clerical errors and to employ more idiomatic English. No new matter has been entered by any of the foregoing amendments.

Claim 29 has been amended to clarify what the terms "FEH" and "($\overline{DP}$)" are meant to refer to. Additionally, all of the process claims 29-49 have been recast as Jepson type claims, i.e. so as to obviate the 112, second paragraph rejection of the claims as being incomplete.

Pursuant to 37 CFR 1.121, marked copies of the specification paragraphs, abstract and claims accompany this amendment.

Turning to the art rejection, the primary reference Van Den Ende et al. is merely a study of the enzymatic activities and occurrence of the enzymatic SST, FFT and FEH (fructan exohydrolase) activities. The study focuses on the growth and harvest of chicory roots in view of the production of Witloof, i.e. Belgian endive. Van Den Ende et al. discloses results about the activities of the enzymes in roots of chicory that are cultivated under conventional growing conditions. However, information that FEH activity increases after mid-October (p. 48) is not sufficient to lead one skilled in the art to any definite particulars about the conditions that trigger FEH activity. In this respect it should be noted that in the area where the test was run, the middle of Belgium, frost commonly does not occur mid-October but commonly only occurs in the beginning of November[1]. Furthermore, the difference is emphasized between frost temperature and the effect of frost on the one hand, and on the other hand, the temperature which triggers the FEH gene (see the present specification page 11, lines 11-27).

[1] The average first day of frost in a region is a matter of public record.

The Van Den Ende et al. disclosure is in fact a publication of a scientific study about the activities and the role of fructan synthesizing/degrading enzymes over various periods of time in the growth and harvest of chicory roots. That is to say, Van Den Ende et al. reports (page 44, left, first paragraph) inulin degradation is believed to be regulated by the combined action of fructosylfructosyltransferase (FFT enzyme) together with fructosyl exohydrolase (one or more FEH enzymes) during the later part of the growing period and during the storage period of harvested roots. However, Van Den Ende et al. neither discloses nor suggests which enzyme is mainly responsible for inulin degradation and/or which conditions trigger the genes which code for said enzyme(s) with inulin degrading activity.

In this respect, it has to be noted too that at the end of the growing season, inulin production decreases and the (DP) of the inulin changes, for reasons which are not quite clear yet. Possible reasons include e.g. (i) the effect of the reduced duration and intensity of daylight and thus of photosynthesis, which in turn results in a significant reduction, up to about a complete stop, of the activity of the sucrose-sucrose-1-fructosyltransferase (1-SST) and thus of the synthesis of 1-kestose which is the essential first building block in the synthesis of inulin, synthesis which is then continued by the action of the 1-FFT enzyme according to the formula

GFF + GFF --{+1-FFT} --› GF + GFFF

GFFF + GFF --{+1-FFT} --› GF + GFFFF, etc.

and/or (ii) a change, possibly an increase, of the activity of the 1-FFT enzyme, which due to the depletion of 1-kestose, catalyzes fructosyl transfer from longer inulin chains to shorter inulin chains, resulting in an overall reduction of the average (DP) (i.e. of ($\overline{DP}$)) according to the formula

GFn + GFn' --{+1-FFT} --› GFn-1 + GFn'+1.

In the above formulae, G represents a glucosyl unit, F a fructosyl unit and n and n' (n > n') represent the number of fructosyl units in the inulin molecule.

Thus, Van Den Ende et al. is publishing results of observations but is not related to a particular problem (the possibility to cultivate chicory outside conventional periods) nor provides a solution nor even any teaching about the possibility to cultivate chicory outside conventional growing periods.

The exact conditions which are responsible for the rapid increase of inulin degradation towards the end of the growing season and during cold storage cannot be identified from Van Den Ende et al. Van Den Ende et al. merely discloses that the activity of FEH rapidly increased after mid-October, but is silent about the exact conditions which trigger said FEH activity. Furthermore, it is common knowledge that the weather conditions in mid-Belgium (the area where Van Den Ende et al. has cultivated the chicory plants for the study reported (see p. 44). Plant material "local field") are quite changeable and, as noted supra, that low temperature conditions according to the subject application hardly occur before the beginning of November. Furthermore, from the results of the study presented in Fig. 4 of Van Den Ende et al., one can derive that the FEH activity increased already from the beginning of October and about steadily increased until the beginning of December. However, the weather conditions in mid-Belgium are commonly such that no low temperature conditions according to the invention or frost occurs in the beginning of October[1]. So it is not clear from Fig. 4 which enzyme was really responsible for the increase of fructose. In fact, from Van Den Ende et al., it appears that the exact conditions which trigger FEH activity are not known at all.

A fortiori, Van Den Ende et al. does not provide any teaching about the way to grow chicory outside the conventional periods, including the specific conditions which trigger the FEH

activity and which may be encountered at a center stage of the cultivation of chicory but which should not occur during another well defined period, as defined in the present claims. Even from Fig. 4 of Van Den Ende et al., one skilled in the art cannot derive the specific temperature conditions which are basic conditions in accordance with the present invention. One skilled in the art would not find any incentive in the prior art to define the FEH triggering conditions in order to cultivate chicory roots outside the conventional growing period in view of using these chicory roots for the manufacture of inulin.

Summarizing to this point, the inventors of the present application have found that degradation of inulin is mainly due to the effect of one or more FEH enzymes (hereinafter termed FEH enzyme) and, in particular, that the gene(s) coding for said enzyme are triggered by specific temperature conditions which are clearly not the same as the conditions causing so-called frost damage. The latter conditions indeed correspond to lower temperatures than the temperature conditions which trigger the FEH gene. Furthermore, arriving at the present invention merely by routine test would require one skilled in the art undue burden in view of the multiple interrelated parameters and conditions as defined in the terms of the present claims.

Van Den Ende et al. does not disclose nor teach a solution to the problem underlying the present invention. Indeed, from the disclosure of Van Den Ende et al., one skilled in the art would still be inclined to cultivate chicory under conventional conditions and wound not be inclined at all to do so under conditions which go beyond the conventional ones. In particular, Van Den Ende et al. does not teach that the sowing and first period of growth may include periods in which lower temperature conditions that trigger the FEH gene may occur. Van Den Ende et al. neither discloses nor suggests which enzyme(s) is/are mainly responsible for degrading inulin in chicory roots at the end of the growing season and/or during harvesting and

storage time, which conditions exactly trigger the activity of the genes including said degrading enzyme(s), and how said inulin degradation could be avoided.

It is not seen that the Van Loo et al. secondary reference supplies the missing teachings to Van Den Ende et al. to achieve or render obvious Applicants' claims. Van Loo et al., which is a prior patent of Smits, one of the named inventors of the subject application, merely relates to inulin that is free of low molecular weight polysaccharides (oligosaccharides) and to a method for the preparation of same. Having regard to the technical problem underlying the present invention, and the technical solution disclosed and claimed in the present patent application, Van Loo et al. merely concerns a preparation of a particular grade of inulin by means of a particular process, but a process that starts from standard grade crude or purified inulin. In the present application, the claims related to such grade of inulin also involve the inventive characteristics of the present invention, namely the particular source material used in the process.

The present claimed invention concerns natural products which are, by their nature, unpredictable. The state of the art at the time of filing of the present application was that inulin in plants, particularly chicory, was considered to degrade at the end of the growing season and during storage, and that the later in the growing season and the longer the storage period, the more the degradation. Furthermore, the art considered that exposure to significant frost, damages chicory roots whether still in the field or harvested and stored. Frost damage destroys plant cell structures as a result of which the roots, when defrosted, rapidly rot with degradation of the reserve carbohydrate, inulin. Accordingly, in Northern Europe (the region where chicory is conventionally cultivated), chicory conventionally is seeded at the end of the season with frost (depending from the occurring weather conditions from about March 15 to May 14), and the

roots are harvested, stored* and processed* (*if not sheltered from frost), preferably and mostly before the roots become exposed to frost.

The present inventors have surprisingly found that temperature conditions which trigger the FEH gene may even occur during a certain period of the growing phase, but that, in order to obtain inulin with a desired high ($\overline{DP}$) (preferably over a long processing period of at least 60 days), the FEH triggering temperature conditions may not occur during a specific period of the growing-harvesting-storage-processing period. This was clearly non-obvious in view of the prior art.

Moreover, it is submitted that the prior art actually teaches away from seeding chicory and having chicory in a first growing phase possibly exposed to low temperature conditions. Thus, a person skilled in the art would not have any reasonable expectation of success, and would not carry out such studies. Therefore, defining the triggering conditions of the FEH encoding gene upon which the present application is non-obvious in view of the prior art.

Besides, from the prior art it was not obvious at all that chicory could be cultivated (including seeding-growing-harvesting-storing and processing) during other time periods and under other climatological temperature conditions than the ones known from the conventional cultivation of chicory.

Furthermore, as a consequence of the elucidation of the conditions which trigger the FEH activity and thus the degradation of inulin, it has become possible, according to the present claimed invention and clearly non-obvious in view of the prior art, to cultivate chicory with longer growing periods, which in turn results in increased yields of chicory roots and consequently in increased yields of inulin.

In summary, the prior art in general, and the primary reference Van Den Ende et al. in particular, neither teaches nor suggests which enzyme is mainly responsible for the degradation of inulin in chicory roots at the end of the growing season and during storage and processing to inulin, nor even more importantly which conditions trigger the production of the enzyme and/or the pronounced FEH activity of the enzyme. Said prior art also neither discloses nor suggests the possibility nor the manner according to the claimed invention to exclude the triggering of the production and/or the activity of said FEH enzyme.

In view of the prior art, it was also clearly non-obvious to obtain by the process of the present invention inulin with a higher mean ($\overline{DP}$) over a long (at least 60 days) storage and processing period than the one of conventional inulin. The prior art indeed teaches away from the claimed invention in this respect, because it is generally known and taught that at the end of the growing period, the ($\overline{DP}$) drops and that thus the chicory roots have to be processed as soon as possible.

Furthermore, considering the long felt need for industrial quantities of inulin product with an improved ($\overline{DP}$) and considering the long period the industry has already had, and failed, to solve this need by means including complicated processing methods as well as biotechnological techniques, it is respectfully submitted that the present claimed invention is non-obvious.

The finality of the restriction requirement is noted. It is submitted that all of the claims are linked by a single general inventive concept. However, so as to be fully responsive, Applicants confirm their election of the process claims, and it is requested that the non-elected claims be maintained in this application, without further action, for possible rejoinder and/or for filing of a Divisional Application.

Having dealt with all the objections raised by the Examiner, the application is believed to be in order for allowance. Early and favorable action are respectfully requested.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on June 27, 2002 at Tucson, Arizona.

By: Diana Carr

MARKED COPY OF SPECIFICATION PARAGRAPHS

SERIAL NO. 09/600,732

DOCKET: TIENSE RAFF.26

MARKED SPECIFICATION PARAGRAPHS:

Paragraph beginning at page 3, line 21:

The degree of polymerisation ($\overline{DP}$) of native chicory inulin ranges from 3 to about 70. The punctual ($\overline{DP}$) of native inulin from chicory roots, which have been grown and processed under known, conventional conditions, ranges from about 10 to 14 (L. De Leenheer, o.c., p. 71), whereas the mean ($\overline{DP}$) of known standard grade chicory inulin, i.e. inulin obtained from chicory roots which have been grown and processed under known, conventional conditions, [is ranging] ranges from about 9 to 11, and is typically about 10.

Paragraph beginning at page 4, line 11:

Inulin is readily dispersible in aqueous liquids, is poorly soluble in cold water but fairly soluble in hot water and shows a good thermal stability. Depending from the presence and concentration of by-products, in particular monosaccharides, disaccharides and oligosaccharides, inulin has a taste ranging from slightly sweet to practically taste free. Inulin in food preparation, may, for example, improve texture and mouthfeel, and contribute to give more body and a smooth, creamy texture in low-fat products. Inulin also improves the stability of emulsions, dispersions, mousses, foams and creams. Furthermore, as disclosed in EP-A- 0 607 187, inulin can form with water a stable, fat-like, creamy structure (when subjected to mixing or shearing forces within a certain range of concentration and temperature). Moreover, inulin itself, i.e. when not taking into account mono- and disaccharides which are possibly present as by-products in the polydisperse polysaccharide, has a low caloric value, because when ingested, it is not digested in the small intestine of humans and many vertebrate animals, but [is] almost

quantitatively [entering] enters the large intestine where it is fermented by bacteria, in particular by bifidobacteria. In view of its unique properties, inulin is widely used as a low calorie sugar replacement, fat replacement and/or texturising agent in various food products, e.g. in chocolate and confectionery products, in baked goods and breakfast cereals, in dairy products, such as desserts, creams, milks, cheeses, and yoghurts, in table spreads, in salad dressings, in fruit preparations, in frozen desserts, in meat products such as e.g. pâtés, and in drinks, as for exampled disclosed in EP-A- 0 599 830, EP-A- 0 607 187, EP-A- 0 607 189, and EP-A- 0 651 614. Moreover, inulin is also widely used in various feed products.

Paragraph beginning at page 11, line 28:

It can be [find out] determined easily whether or not the FEH gene in the chicory roots has been triggered because triggering of the FEH gene is marked by a significant increase in concentration of fructose in the chicory roots (see equation (3a) and (3b) above).

Paragraph beginning at page 13, line 3:

In a preferred embodiment, the climatological temperature conditions are such that the FEH [gen] gene is not triggered neither during a processing period of 60 days, more preferably 90 days, adjacent to the growing period.

Paragraph beginning at page 25, line 35:

Harvest was done manually [two-weekly] every two weeks from 16/09 until 10/12 and the roots were processed without delay.

MARKED COPY OF AMENDED CLAIMS

SERIAL NO. 09/600,732

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MARKED CLAIMS SHOWING CHANGES MADE:

29. (Amended) [Process] In a process for the manufacture of chicory inulin from chicory roots through conventional manufacturing techniques, [characterized in that] the improvement wherein:

- the source material for the process are roots of chicory which have been grown in appropriate regions and have been grown and processed under proper climatological temperature conditions which are such that during a period of at least from the beginning of the third month of the growing period till the end of the processing of the chicory roots the [FEH] fructan exohydrolase (FEH) gene in the chicory roots has not been triggered by the occurrence of low temperature conditions,
- said chicory roots have had a growing period of at least 150 days,
- said chicory has been seeded
  - in the northern hemisphere within a period selected from the periods ranging from December 1 till March 14, from March 15 till May 14, from May 15 till May 31, from June 1 till June 14, and from June 15 till November 30, provided that when said chicory has been seeded in the periods from May 15 till May 31, and from June 1 till June 14, the chicory roots have had a growing period of at least 180 days, and provided that when said chicory has been seeded in the period from March 15 till May 14, the chicory roots have been grown and processed under climatological conditions wherein, within a period of at least 220 consecutive days immediately preceding the end of the processing of the roots, no low temperature conditions occurred which triggered the FEH gene, and the chicory roots have had a minimum growing period of at least 160 days,

- in the southern hemisphere within a period selected from the periods ranging from June 1 till September 14, from September 15 till September 30, from October 1 till November 14, from November 15 till November 30, and from December 1 till May 31, and

- the inulin obtained is

  - standard grade or low sugar standard grade chicory inulin with a degree of polymerisation ($\overline{DP}$) of at least 10, or

  - improved standard grade or improved low sugar standard grade chicory inulin with a mean ($\overline{DP}$)of at least 12, or

  - high performance grade chicory inulin with a ($\overline{DP}$) of at least 20, or

  - improved high performance grade chicory inulin with a mean ($\overline{DP}$) of at least 20,

  - with the mean ($\overline{DP}$)being taken over a processing period of at least 60 days.

30. (Amended) [Process] In a process according to claim 29, the improvement wherein the chicory has had a growing period of at least 180 days.

31. (Amended) [Process] In a process according to claim 29, the improvement wherein the chicory has been seeded in the northern hemisphere.

32. (Amended) [Process] In a process according to claim 29, [for the manufacture of improved standard grade chicory inulin,] the improvement wherein the roots of chicory have been grown and processed under climatological temperature conditions wherein, within a period of at least 220 consecutive days immediately preceding the end of the processing of the roots, no low temperature conditions occurred which triggered the FEH gene in chicory roots, said roots have had a growing period of at least 160 days, and the inulin obtained is improved standard grade chicory inulin with a mean ($\overline{DP}$) taken over a processing period of at least 60 days, which is at least 12.

33. (Amended) [Process] In a process according to claim 32, the improvement wherein no low temperature conditions which trigger the FEH gene in chicory roots occur within a total period of at least 240 consecutive days and the chicory has had a growing period of at least 180 days.

34. (Amended) [Process] In a process according to claim 33, the improvement wherein the chicory has been seeded in the northern hemisphere within a period selected from the periods ranging from December 1 till March 14, from March 15 till May 14, from May 15 till May 31, and from June 1 till November 30, or in the southern hemisphere within a period selected from the periods ranging from June 1 till September 14, from September 15 till November 14, from November 15 till November 30, and from December 1 till May 31.

35. (Amended) [Process] In a process according to claim 29, the improvement wherein the said climatological temperature conditions are such that during the concerned period immediately preceding the end of the processing of the chicory roots the temperature in the [temperature shelter has not] region shall not have dropped below minus 1°C.

36. (Amended) [Process] In a process according to claim 29, the improvement wherein said appropriate regions comprise the Californian region of the USA.

37. (Amended) [Process] In a process according to claim 29, [for the manufacture of standard grade chicory inulin or improved standard grade chicory inulin,] the improvement wherein the source material are chicory roots which have been grown and processed under the conditions as defined in claim 29, said process further comprising the steps of:

(i) isolation of the inulin from the chicory roots yielding an aqueous solution of crude inulin,

(ii) purification of the crude inulin obtained in step (i) yielding an aqueous solution of purified inulin, optionally followed by concentration of this solution by partial removal of the water yielding a purified inulin concentrate, and

(iii) isolation in particulate form of the inulin from the aqueous solution or concentrate of purified inulin obtained in step (ii), thereby yielding, respectively, standard grade chicory inulin or improved standard grade chicory inulin.

38. (Amended) [Process] In a process according to claim 37, the improvement comprising:

- for step (i): extraction with hot water of the inulin from fresh slices or shreads of the chicory roots, yielding an aqueous solution of crude inulin,

- for step (ii): purification of the aqueous solution of crude inulin obtained in step (i) by depuration followed by refining, and

- for step (iii): isolation of, respectively, standard grade chicory inulin or improved standard grade chicory inulin, in particulate form by spray drying.

39. (Amended) [Process] In a process according to claim 29, for the manufacture of low sugar standard grade chicory inulin or improved low sugar standard grade chicory inulin containing in total less than 1 weight % monomeric saccharides and sucrose, by conventional techniques from chicory roots, the improvement wherein the source material are chicory roots which have been grown and processed under the conditions as defined in claim 29.

40. (Amended) [Process] In a process according to claim 39, the improvement wherein, respectively, standard grade chicory inulin or improved standard grade chicory inulin or [the] a corresponding intermediate purified inulin, obtained by a process defined in claim 29 is used as a

source material and is, in accordance with known techniques, subjected to the following additional consecutive steps:

(iv) removal of the monomeric saccharides and sucrose, yielding a low sugar inulin solution or concentrate, and

(v) isolating the low sugar inulin in particulate form from the solution or concentrate obtained in step (iv),

and the product obtained is, respectively, low sugar standard grade chicory inulin with a mean ($\overline{DP}$) of at least 10 or improved low sugar standard grade chicory inulin with a mean ($\overline{DP}$) of at least 12, the mean ($\overline{DP}$) being taken over a processing period of at least 60 days.

41. (Amended) [Process] In a process according to claim 29, for the manufacture of high performance grade chicory inulin with a ($\overline{DP}$) of at least 20, or improved high performance grade chicory inulin with a mean ($\overline{DP}$), taken over a processing period of the chicory roots of at least 60 days, of at least 20, which are essentially free from low molecular monomeric saccharides, dimeric saccharides and oligofructose, and essentially free from colorings, salts, proteins, organic acids and technological aids, the improvement wherein the source material are chicory roots which have been grown and processed under the conditions as defined in claim 29.

42. (Amended) [Process] In a process according to claim 41, the improvement wherein standard grade chicory inulin with a ($\overline{DP}$) of at least 12, respectively improved standard grade chicory inulin with a mean ($\overline{DP}$), taken over a processing period of the chicory roots of at least 60 days, of at least 12, or its intermediate, depurated or refined inulin, obtained by a process defined in claim 29, is used as a source material and subjected, in accordance with known techniques, to the following consecutive steps:

(vi) fractionation, and

(vii) isolation in particulate form of the high performance grade inulin from the fractionated product obtained in step (vi),

thereby providing high performance grade chicory inulin, respectively improved high performance grade chicory inulin in a yield of at least 40% based on the source inulin.

43. (Amended) [Process] In a process according to claim 42, the improvement wherein the fractionation is carried out by directed crystallization of an aqueous metastable solution of the source material, and the isolation of the fractionated inulin in particulate form is carried out by filtration or centrifuging including washing with water.

44. (Amended) [Process] In a process according to claim 42, the improvement wherein the source inulin has a (DP), respectively a mean ($\overline{DP}$) of at least 14, and the high performance grade chicory inulin, respectively improved high performance grade chicory inulin, is obtained in a yield of at least 45% based on the source material, and has a ($\overline{DP}$), respectively a mean , of at least 20, the mean ($\overline{DP}$) being taken over a processing period of the source chicory roots of at least 60 days.

45. (Amended) [Process] In a process for the manufacture of a partial hydrolysate of chicory inulin, by conventional techniques from chicory roots, the improvement wherein the source material are chicory roots which have been grown and processed under the conditions as defined in claim 29 and the product obtained in polydisperse oligofructose.

46. (Amended) [Process] In a process according to claim 45, the improvement wherein respectively, standard grade or improved standard grade chicory inulin or the corresponding intermediates, depurated or refined inulin, obtained by a process defined in claim 29, is used as a source material, and the product obtained is polydisperse oligofructose containing at least 90% by weight dry substance and the oligofructose has a ($\overline{DP}$) from 2 to 10.

47. (Amended) [Process] In a process for the manufacture of a complete hydrolysate of chicory inulin, by conventional techniques from chicory roots, the improvement wherein the source material are chicory roots which have been grown and processed under the conditions as defined in claim 29, and the product obtained is fructose.

48. (Amended) [Process] In a process according to claim 47, the improvement wherein, respectively, standard grade or improved standard grade inulin or the corresponding intermediate, depurated or refined inulin, obtained by a process defined in claim 29, is used as a source material, and the product obtained is fructose containing at least 89% by weight fructose, calculated on dry substance.

49. (Amended) [Process] In a process for the manufacture of a derivative of chicory inulin, by conventional techniques from chicory inulin or an intermediate thereof, the improvement wherein the source material for the inulin are chicory roots which have been grown and processed under the conditions as defined in claim 29.

MARKED ABSTRACT

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MARKED ABSTRACT SHOWING CHANGES MADE:

[The invention provides an] An improved process for the manufacture of chicory inulin, hydrolysates and derivatives of inulin by conventional manufacturing techniques from roots of chicory grown in appropriate regions and which have been grown and processed under proper climatological temperature conditions. Selection of [said] proper conditions enables to provide a growing and/or processing period for the chicory roots which may partly or wholly extend beyond [the] conventional periods. [The invention relates also to improved] Improved grades of chicory inulin, i.e. having a degree of polymerisation (DP) which is at least 20% higher than the one of conventional standard grade chicory inulin, of hydrolysates of chicory inulin, such as e.g. a polydisperse oligofructose composition and a fructose composition[,] are obtained. The resulting [as well as to the use of these] products may be used in the manufacture of food, feed, drinks, prophylactic and therapeutical compositions, chemical derivatives and non-food compositions.

[Improved standard grade chicory inulin according to the invention present a degree of polymerisation ($\overline{DP}$) which is at least 20 % higher than the one of conventional standard grade chicory inulin.]